

K122545

SEP 20 2012

6 510(K) SUMMARY

Submitter Information

Name: Arrow International, Inc (subsidiary of Teleflex Inc.)
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Date Prepared: August 20, 2012

Device Name

Device Trade Name: CG+ Arrow PICC powered by Arrow VPS Stylet
Common Name, Catheter: Peripherally Inserted Central Catheter (PICC)
Common Name, Stylet: Catheter, Ultrasound, Intravascular

Classification Name, Catheter: Percutaneous, implanted, long-term intravascular catheter per 21 CFR: 880.5970

Classification Name, Stylet: Diagnostic Intravascular Catheter per 21 CFR 870.1200

Predicate Devices

- K103255: Vascular Positioning System (VPS System) Stylet
- K112896: Pressure Injectable PICC with Chlorag+ard Antimicrobial and Antithrombogenic Technology

Device Description

The CG+ Arrow PICC powered by Arrow VPS Stylet has the following characteristics:

- 4.5 Fr, 1-Lumen, 40-55 cm pressure injectable, antimicrobial and antithrombogenic catheter preloaded with VPS Stylet

The CG+ Arrow PICC is pre-loaded with the Arrow VPS Stylet and will be provided in sterile kit configurations.

The Arrow Pressure Injectable PICC with Chlorag+ard Antimicrobial and Antithrombogenic Technology is a short-term or long-term, single use catheter designed to provide access to the central venous system. It consists of a non-tapered, radiopaque polyurethane extruded catheter body with a softer, contoured Blue Flex Tip. The catheter can be used for the injection of

contrast media. The maximum recommended infusion rate is 5 mL/sec. The external catheter body and the internal fluid path of the device are treated with Chlorhexidine based solution technology. Studies have shown the technology to possess both antimicrobial and antithrombogenic properties.

The Arrow VPS Stylet is a polyimide tube containing a Doppler sensor on a coax cable and an intravascular electrocardiogram (ivECG) signal sensing stainless steel wire. The Doppler sensor and the exposed portion of the ivECG are located at the distal end of the stylet and are used to detect and transmit physiological information to the VPS Console for analysis. The proximal end contains a connector to the VPS Console or to an extension cable that in turn connects to the VPS Console. The stylet was designed to be able to be inserted and removed from any catheter with a luminal diameter of at least 0.021 inch.

For user convenience, Arrow has created the CG+ Arrow PICC powered by Arrow VPS Stylet in which the Arrow Pressure Injectable PICC with Chlorag+ard Antimicrobial and Antithrombogenic Technology is provided pre-loaded with the Arrow VPS Stylet.

Intended Use

A PICC permits venous access to the central circulation through a peripheral vein.

The intended use of the VPS Stylet and Console (VPS System) is to quickly and accurately guide market available central catheters to the desired location which is the lower third of the SVC or at the cavo-atrial junction.

Technological Characteristics and Substantial Equivalence

The CG+ Arrow PICC powered by Arrow VPS Stylet is substantially equivalent to the Vascular Positioning System (VPS System) Stylet (K103255) and the Pressure Injectable Peripherally Inserted Central Catheter (PICC) with Chlorag+ard Antimicrobial and Antithrombogenic Technology (K112896) in terms of indications for use, design, manufacturing process, functional performance, and materials of construction. The subject device combines the predicate Arrow VPS Stylet and the Arrow Pressure Injectable PICC with Chlorag+ard Antimicrobial and Antithrombogenic Technology; there is no change to the previously cleared devices or their indications for use.

Nonclinical Testing

The following testing was performed on the CG+ Arrow PICC powered by Arrow VPS Stylet: catheter performance testing: air and liquid leakage, stylet performance testing: tensile, electrical function and removal testing and the combined device performance testing: simulated use insertion/removal test.

Conclusions

The predicate and the subject devices have the same indications for use, intended use, design, materials, and are manufactured using the same processes. The results of the testing performed have demonstrated that combining the two previously cleared devices does not raise new issues of safety or effectiveness and therefore the combination is considered substantially equivalent to the cited predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

SEP 20 2012

Arrow International, Inc.
c/o Ms. Elizabeth Duncan
Sr. Regulatory Affairs Specialist
2400 Bernville Road
Reading, PA 19605

Re: K122545

Trade/Device Name: CG+ Arrow PICC powered by Arrow VPS Stylet
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous Implanted Long-Term Intravascular Catheter
Regulatory Class: Class II
Product Code: LJS, OBJ
Dated: August 20, 2012
Received: August 21, 2012

Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

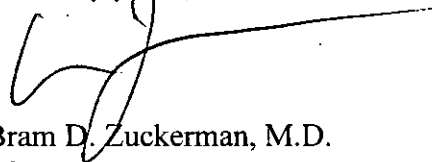
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Bram D. Zuckerman', with a long horizontal line extending to the right.

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122545

Device Name: **CG+ Arrow PICC powered by Arrow VPS Stylet**

Indications for Use:

The Pressure Injectable PICC with Chlorag+ard Antimicrobial and Antithrombogenic Technology is indicated for short-term or long-term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion, pressure injection of contrast media and allows for central venous pressure monitoring. The maximum pressure of pressure injection equipment used with the pressure injectable PICC catheter may not exceed 300 psi.

Chlorag+ard Technology treatment on the external surface of the catheter body as well as the entire fluid pathway of the catheter has been shown to be effective in reducing microbial colonization and thrombus accumulation on catheter surfaces. Antimicrobial and antithrombogenic effectiveness were evaluated using *in vitro* and *in vivo* test methods and no correlation between these test methods and clinical outcome has currently been ascertained. It is not intended to be used for the treatment of existing infections or vein thrombosis.

The VPS Stylet and Console are indicated for guidance and tip positioning for central venous catheters. The Stylet provides stiffness for use in placement of the catheter, intravascular capability for ECG detection and recording and intravascular ultrasound for catheter guiding and positioning. The VPS Stylet, when used with the VPS Console, provides real-time catheter tip location information by using the patient's physiological (cardiac electrical activity and blood flow) information. When the VPS System guidance indicator shows a Blue Bullseye, the catheter tip is in the desired location.

The VPS System is indicated for use as an alternative method to fluoroscopy or chest x-ray for central venous catheter tip placement confirmation in adult patients when a steady Blue Bullseye is obtained. NOTE: If a steady Blue Bullseye is not obtained, standard hospital practice should be followed to confirm catheter tip location.

Limiting but not contraindicated situations for this technique are in patients where alterations of cardiac rhythm change the presentation of the P-wave as in atrial fibrillation, atrial flutter, severe tachycardia and pacemaker-driven rhythm, and in central venous catheterization procedures performed through femoral or saphenous vein access which change the presentation of the P-wave. In such patients, who are easily identifiable prior to central venous catheter insertion, the use of an additional method is required to confirm catheter tip location.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division of Cardiac Devices)

Division of Cardiovascular Devices

510(k) Number

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